REMARKS

Claims 1-25 and 32-33 are pending. Claims 26-31 were cancelled in response to a prior restriction requirement. By this Amendment, claims 3, 7, 11, 15, 18-25 and 32-33 are withdrawn. As a result, claims 1-2, 4-6, 8-10, 12-14 and 16-17 should be pending.

Interview Summary

The Applicants' attorney thanks the Examiner for the telephonic interview of January 7, 2004, during which the matter of which claims read on which species and figures was discussed, along with a general discussion of the prior art reference cited in the Office Action. It was agreed that Applicants would prepare and submit a response addressing the issue of which claims should be withdrawn and which claims read on the elected species. No agreement was reached with respect to the prior art or claims.

Election/Restrictions

Based on the telephonic interview, it appears that there was confusion about the nature of the elected species arising out of an apparent confusion over two different embodiments of the handheld apparatus of the present invention. As indicated at page 10, lines 22-24 of the specification, the present invention contemplates two different types of handheld apparatus – a first handheld apparatus that encompasses only the sealing system 60, and a second handheld apparatus that includes both the sealing system 60 and the inflation/evacuation system 80.

Figs. 7-9, for example, are directed to the species of the first handheld apparatus comprising only the sealing system 60 as a handheld apparatus and including a second aperture 64 that is fluidly connectable to the inflation/evacuation system 80. (It will be noted that the inflation/evacuation system 80 in the embodiment shown in Figs. 7-9 of this species is also separably hand operated, although it is not intended that this be a limitation of this species.)

Figs. 5-6, on the other hand, are directed to the species of the second handheld apparatus comprising both the sealing system 60 and the inflation/evacuation system 80.

Figs. 1 and 2 depict an early embodiment of the present invention that more clearly shows the internal fluid conduits and could be arranged in accordance with either of the handheld species.

Applicants acquiesce to the withdrawal of claims 3, 7, 11, 15, 18-25 and 32-33 for purposes of the prosecution of this application until the indication of allowable subject matter with respect to a generic claim.

Applicants respectfully submit that claims 5-6, 10, 12-14 and 16-17 do read on the elected second species of handheld apparatus and traverse the withdrawal of these claims. With respect to claims 5-6 and 12-14, it will be noted that the features with respect to a pivoting roller mechanism are shown, for example, in connection with Figs. 12-14 that provide details of a preferred embodiment of the sealing system 60 used as part of the elected species shown in Figs. 1, 2, 5 and 6. With respect to claim 10, it is respectfully submitted that the elected species as shown in Figs. 1, 2, 5 and 6 does show a sealing system that is "removably connectable to the proximal portion of the guidewire assembly." While the sealing system itself is part of the handheld apparatus, the removable connection has been claimed in terms of being removably connection to the guidewire. In one embodiment as shown, the guidewire may be inserted into and removed from a first aperture 62 of the sealing system 60.

Drawings

The drawings were objected to as not showing the handheld apparatus of the elected species. In light of the discussion set forth above with respect to the two species of handheld apparatus, it is respectfully requested that this rejection be withdrawn.

Applicants are in the process of having formal drawings prepared for the application that will be augmented to include additional call outs of elements in different figures having common reference numerals. The formal drawings, any proposed drawing corrections to the drawings and, if necessary, to the Brief Description of The Drawings will be submitted upon completion of the formal drawings.

35 U.S.C. § 112 Rejections

Claim 2 was rejected as not providing antecedent basis for the limitation of the handheld apparatus. In light of the discussion set forth above with respect to the two species of handheld apparatus, it is respectfully requested that this rejection be withdrawn.

Claim Rejections – 35 USC 102(e)

Pending claims 1, 2 and 4 were rejected under 35 U.S.C. § 102(e) as being anticipated by anticipated by Valley et al (U.S. Patent No. 6,251,093). These rejections are respectfully traversed.

It is respectfully submitted that a catheter displaced within a delivery cannula and having a liquid filled occlusion balloon for use as an intra-aortic occlusion device as part of a heart bypass procedure is a medical apparatus that it entirely different than a guidewire assembly for which the gas inflation/evacuation system of the present invention is designed. The use of such catheter based devices and even intra-aortic occlusion devices are discussed extensively in the Background section of the application (Specification, page 2, line 22-25 and page 5, lines 15-20). With respect to the intra-aortic occlusion device of the type described by Valley et al., such devices are not designed to be used as guidewires and have no ability to track a catheter or other "over-the-wire" tubular medical apparatus over the longitudinal length of the device. To be used as a conventional exchange guidewire, the present invention preferably utilizes a tubular member having an outer diameter of less than 0.060 inches (Specification, page 8, line 5), a dimension that translates into an outer diameter of less than about 2 mm or 5 French. In contrast, the tubular catheter arrangement described by Valley et al. has an outer diameter that ranges from 8 – 23 French (Col. 15, lines 43-44) or 3-4 mm (Col. 40, line 7). It is simply not physically possible for the catheter arrangement described by Valley et al. to be used as a guidewire member in accordance with the present invention.

Even if Valley et al. were somehow applicable to a guidewire arrangement, which it is not, the disclosure of Valley et al. does not provide support for each and every limitation of the claimed invention. In the preferred embodiment of the aortic occlusion balloon 110 as described in Cols. 15 and 16 of Valley et al., the balloon 110 is inflated with saline and the balloon inflation lumen is preferably at least 0.5 mm^2– 1.0 mm^2 in cross-sectional area in order to permit rapid inflation and deflation of the balloon 110 *using a liquid as the inflation medium.* The reference in paragraph 8 of the Office Action to a "means for evacuating air from the guidewire assembly" directly references a discussion of inflation and deflation of the balloon 110 using saline. There is simply nothing in this section of Valley et al. that provides any support for disclosing a means for *evacuating air* from a guidewire assembly.

The only reference in Valley et al. to the use of a gas for inflation of the occluding balloon is an offhand reference in Col. 13 at lines 45-50, which is cited in paragraph 8 of the Office Action. "Alternatively, the occluding balloon 60 may be partially inflated with air or CO_2 *during introduction for flow assisted placement.*" (Col. 13, lines 45-46). There is nothing about this passage that provides support to anticipate the claimed limitation of "introducing a biocompatible gas into the guidewire assembly to inflate an occlusive balloon . . . *a plurality of times.*" At best, and assuming that Valley et al. was somehow applicable to a guidewire assembly, the disclosure of Valley et al. expressly suggests only that *partial* inflation using air or CO_2 might be done during *initial* placement of the balloon.

It is respectfully submitted that the discussion of clamp sites 856 in Col. 38 of Valley et al. that is cited in paragraph 8 of the Office Action as support for a "means for selectively sealing the proximal portion of the guidewire assembly" is ineffective in providing this support. The clamp site 856 and a proximal clamp site 864 are both on the body of a special arterial bypass cannula 850 as described at the bottom of Column 37. The endoaortic partitioning catheter 895 on which the occlusion balloon 896 is positioned is routed into the bypass cannula 850 according to the procedure as described at Col. 42, lines 30 to Col. 43, line 16 of Valley et al. The procedure specifically describes how the clamp 891 (as shown in Fig. 33) is used to stop the flow of blood out of the bypass cannula 850 in order to permit the endoaortic partitioning catheter 895 to be inserted into the adapter 876. Once inserted, however, "the clamp 891 can be removed to allow the catheter 895 to be advanced distally through the arterial bypass cannula 850." (Col. 42, lines 50-52). It is respectfully submitted that a person of ordinary skill in the art will recognize that the clamp 891 and clamp sites 856 and 864 are intended only to stop the flow of blood out of the bypass cannula 850 and are expressly not used when the catheter 895 with the occlusion balloon 896 is advanced into the bypass cannula 850. As such, there is nothing in Valley et al. that teaches or suggests clamping the catheter 895 for purposes of sealing the inflation of occlusion balloon 896.

With respect to dependent claim 2, it is respectfully submitted that Valley et al. does not teach a handheld pump. It is respectfully submitted that the reference at the top of Col. 16 to inflation by hand is referring to hand inflation with saline by a syringe. As such, the assertion that the system of Valley et al. has "a pump that adds/removes air" is not supported.

With respect to dependent claim 4, it is respectfully submitted that Valley et al. does not teach a crimping mechanism for sealing a guidewire for the reasons set forth above.

Claim Rejections – 35 USC 103(a)

Pending claims 8 and 9 were rejected under 35 U.S.C. § 103(a) as being obvious over Valley et al. (U.S. Patent No. 6,251,093). These rejections are respectfully traversed.

While it is admitted that packaging a medical device in a sterile package may be obvious, it is respectfully submitted that without the hindsight afforded by the present invention in terms of use of a biocompatible gas as an inflation medium, there is simply nothing in Valley et al. that teaches or suggests the limitations of dependent claim 9.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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